Vari-Lase®
Endovenous Laser Console

User's Manual

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Vari-Lase Endovenous Laser Console, Instruction Manual Copyright 2009-2010

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Caution

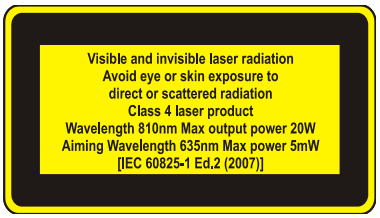
1. The Vari-Lase laser console is a Class 4 laser, which emits invisible laser radiation.
2. Avoid exposure to direct or scattered radiation.
3. Patient, operator and others in contact with the laser must wear suitable protective eyewear. Protective eyewear must be of a quality corresponding to the standards IEC 60825 and EN 207.
4. Read the operating instructions thoroughly before connecting the laser unit to power and prior to use. The laser unit must be set, regulated and used in accordance with the instructions for use. Failure to observe usual safety precautions may present a risk of hazardous exposure to laser radiation.
5. When the laser unit is not in use, ensure that it is rendered inaccessible to unauthorized personnel. Remove the key to disable the laser unit.

Restrictions on use of Class 4 laser equipment

U.S. Federal Law restricts this device to sale by or on the order of a physician.

The Vari-Lase laser system is intended solely for physicians trained in the use of these instruments. The safety precautions for Class 4 laser equipment must be followed. The physician is responsible for evaluating each patient's suitability to undergo laser surgery and furthermore to inform the patient about any risks involved, the actual treatment, pre- and postoperative care and any other relevant information.

These warning labels are placed on the laser unit


Visible and invisible laser radiation
Avoid eye or skin exposure to
direct or scattered radiation
Class 4 laser product
Wavelength 810nm Max output power 20W
Aiming Wavelength 635nm Max power 5mW
[IEC 60825-1 Ed.2 (2007)]

Introduction

Congratulations on the purchase of this Vari-Lase laser console, among the most advanced and user-friendly diode lasers available. It constitutes the fruition of many years of experience in the manufacturing and development of high technology medical laser equipment.

The Vari-Lase laser console is fed by a diode laser module, which can provide a continuous or pulsed wave laser beam. It has a highly intelligent user interaction system - even though it is a very compact system.

Rigorous quality control and factory testing ensure the very highest levels of quality and reliability.

The laser unit incorporates various fail-safe systems and conforms to international standards for medical electrical equipment, IEC 60601-1 and those specifically for laser equipment IEC 60601-2-22 and IEC 60825.

This manual is intended to provide you with an overview of the operation of this laser console. Further instructions regarding its use in particular situations may be obtained in the Instructions For Use provided with the Vari-Lase Endovenous Laser Procedure Kit.

Intended Use

The Vari-Lase laser console operates with a wavelength of 810nm. The 810nm wavelength is primarily absorbed in melanin, hemoglobin and dark tissue and only a limited amount of the light is absorbed in water. This enables a fast heat increase in the irradiated area, leading to effective heating of tissue at low output power.

Indications

The Vari-Lase procedure is indicated for the treatment of varicose veins and varicosities associated with superficial reflux of the Great Saphenous Vein and for treatment of incompetence and reflux of superficial veins in the lower extremity.

Contraindications

The Vari-Lase procedure is contraindicated in patients with an aneurismal section in the vein segment to be treated.

The Vari-Lase procedure is contraindicated in patients with severe peripheral vascular disease, as evidenced by an ankle-brachial index of < 0.5.

The Vari-Lase procedure is contraindicated in patients with thrombus in the vein segment to be treated.

Warnings

Treatment of a vein located close to the skin surface may result in a skin burn.

Paresthesia may occur from thermal damage to adjacent sensory nerves.

Appropriate eye protection must be worn by the patient and all operating personnel to protect from damage by direct or reflected laser energy.

Complications

As with all medical procedures, complications may occur. For the endovenous laser treatment of varicose veins, these may include:

- vessel perforation
- thrombosis
- pulmonary embolism
- phlebitis
- hematoma
- infection
- paresthesia
- skin burns

Precautions

The Vari-Lase procedure should be performed only by physicians who are thoroughly trained in percutaneous, endovenous techniques and procedures and knowledgeable in the use of this laser console.

Inspect the laser fiber before use and avoid touching the laser lenses and Vari-Lase endovenous laser fiber ends to avoid damage to the fiber

and the instrument optics.

Exercise care in handling of the Vari-Lase endovenous laser fiber during the procedure to reduce the possibility of accidental breakage, bending or kinking.

Important Note

Additional information concerning laser fiber handling and use can be found in the instruction manual provided with the Vari-Lase endovenous laser fiber.

Clinical Procedure

Follow the Instructions for Use accompanying the endovenous laser procedure kit and components being used, and accepted medical practice. The techniques, procedures and equipment described do not represent ALL medically acceptable protocols, nor are they intended as a substitute for the physicians experience and judgment in treating any specific patient.

Each Vari-Lase Endovenous Laser Procedure will require the following components:

- Vari-Lase 810nm Laser Console
- Safety eyewear for patient and all operating personnel
- Duplex ultrasound console and transducer for mapping and guidance
- Procedure kit and sterile procedure pack

Installation and User Obligations

The Vari-Lase laser console is designed to operate within normal room temperature (15-27°C / 59-81°F) and humidity conditions. The unit must be allowed to acclimatize before use following exposure to extreme temperature or humidity. Do not install the unit close to radiators or other sources of heat convection.

The Vari-Lase laser console may overheat due to excessive room temperature in combination with operation at high output power. In case of overheating the laser unit will automatically shut down for a short cooling period. After a few seconds the laser unit will be ready for continued treatment.

We advise against the use of lasers at a distance of less than 2.5m from short-wave or microwave equipment, since unstable laser irradiation may occur.

No attempt should be made by unauthorized persons to open the Vari-Lase laser console with intent to repair. Failure to observe this caution may present a serious safety hazard and will void warranty.

Vascular Solutions, Inc. cannot be held liable for events resulting from negligence, abuse or incorrect operation of the unit. Please acquaint yourself thoroughly with the instructions for use, and in the event of doubt contact Vascular Solutions, Inc.

Important Safety Information

The Vari-Lase laser console is designed and tested for maximum safety for both the user and patient. It is, however, ultimately the operator's responsibility to introduce safe practices which ensure the safety of personnel and equipment.

WARNING

Only Vascular Solutions authorized personnel should attempt to inspect and/or repair the Vari-Lase laser console. The Vari-Lase laser console contains no user serviceable parts

Electrical safety

The system must be grounded.

Optical safety

Avoid exposure to laser radiation in excess of the allowable limits listed in Title 21 U.S. Code of Federal Regulation, parts 1040.10 and 1040.11, during the installation and operation of the Vari-Lase laser console.

WARNING

Injury to the eyes and the epidermis can result from either direct or scattered radiation. The power density of the light emitted from lasers can be high enough to cause severe burns to the skin when directly exposed to the beam.

WARNING

All personnel in the operating room must be protected from stray and scattered radiation by wearing the appropriate protective eyewear to guard against ocular injury. Never look directly into any laser beam.

Use surgical instruments with a dull and dark anodized finish whenever possible. Shiny surfaces can reflect laser beams. Take extreme care if shiny surgical instruments are used.

Fire and explosion precautions

Combustible material can ignite if exposed to certain wavelengths of laser radiation.

WARNING

Do not operate the laser in the presence of explosive gases and liquids as well as highly concentrated oxygen.

The following precautions can minimize the risk of fire:

a. Surround the surgical field with wet gaze or towels
b. If possible, eliminate flammable materials from the surgical field
c. Have a fire extinguisher nearby

Always place the laser unit in **Standby Mode** whenever possible. This will prevent accidental firing of the laser.

Precautions against transfer of diseases

The cleansing and sterilization instructions provided by this manual shall always be followed to avoid transfer of diseases through patient contact with operation components.

WARNING

Insufficient cleansing or sterilization of operation components that get in contact with the patient may result in transfer of diseases.

Precautions against toxic effects

When undertaking endovenous treatments, it is of utmost importance that all materials introduced into the veins of the patient, are fully bio-compatible.

WARNING

Material without properly certified bio-compatibility must never be used for endovenous laser treatment.

Precautions against embolic hazard

Caution

The Vari-Lase Endovenous Laser Procedure Kit is designed for single use only. Reuse of the fiber may result in hot spots causing combustion and embolization of fiber fragments.

Precautions against hazardous radiation exposure

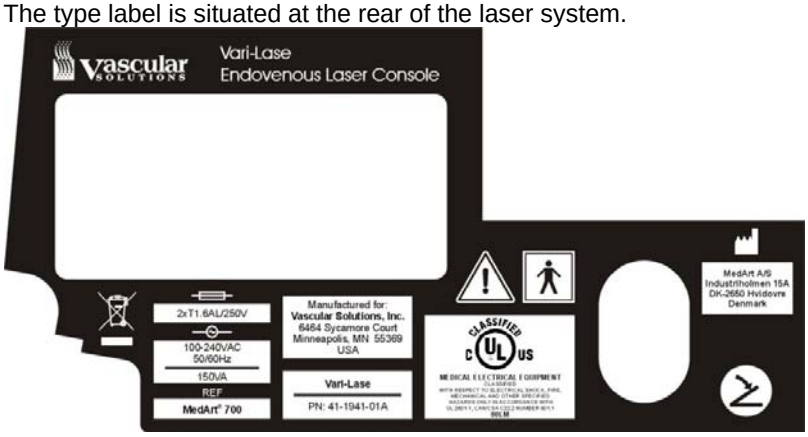
To ensure a safe and efficient treatment, the user must always follow the procedures of this manual.

Caution

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Labels and Symbols

The type label is situated at the rear of the laser system.



Specifies the rating of the power supply.

Specifies the ratings of the fuses to be used for the equipment.

Specifies Type BF Applied Part (Body Floating).

European Directive 2002/96/EC requires that equipment bearing this symbol must not be disposed of with unsorted municipal waste.

Indicates the foot switch inlet.

"Manufactured for:"

Specifies the name and address of the corporation which distributes the equipment within the United States. Please note; this corporation is not the same as the manufacturer.

Serial number label is situated at the rear panel of the laser.

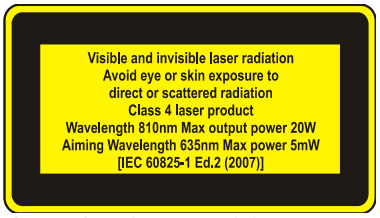
The interlock label is situated under the front panel of the laser system.

A Service connector A. **For service use only.**

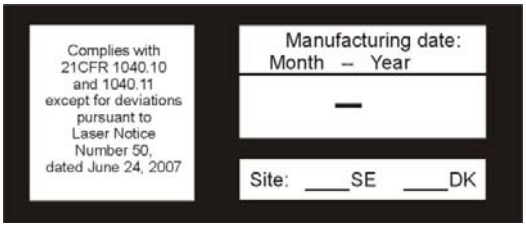
B Service connector B. **For service use only.**

Interlocking socket. See paragraph "Remote Interlocking" on page 17.

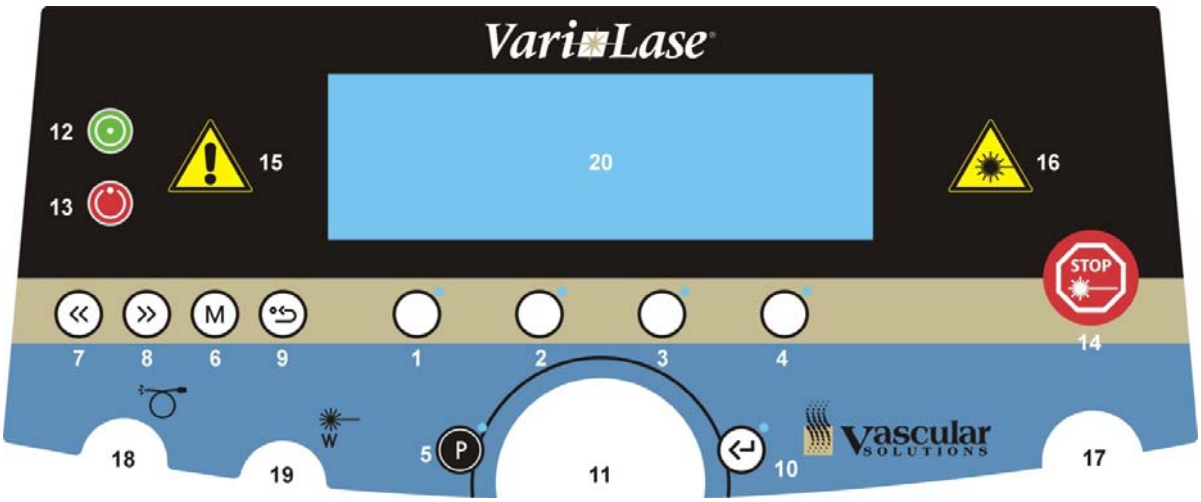
Explanatory label and Laser Warning label is affixed visible on the front-top of the system.


Visible and invisible laser radiation
Avoid eye or skin exposure to
direct or scattered radiation
Class 4 laser product
Wavelength 810nm Max output power 20W
Aiming Wavelength 635nm Max power 5mW
[IEC 60825-1 Ed.2 (2007)]

CDRH and production date label – situated at the rear of the system.



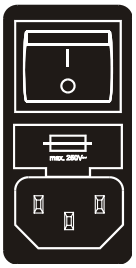
Description of Operating Console



Vari-Lase laser console

1-4	Selector keys	Parameter selection - accompanying LED lit when active
5	Program key	Provides the possibility of choosing any pre-programmed set of treatment parameters - accompanying LED lit when active
6	Menu key	Provides access to the various menus featured by the Vari-Lase laser console
7	Left key	Used for menu browsing and operation
8	Right key	Used for menu browsing and operation
9	Back key	Used for stepping upwards in the menu hierarchy and leaving the selected menu item without saving changed parameters
10	Enter key	Confirms/saves the parameters currently displayed - accompanying LED lit when active
11	Jog wheel	Turning the jog wheel clockwise will increase any selected parameter, turning it counter-clockwise will decrease the parameter
12	Ready key	When activated the Vari-Lase laser console is set into **Ready Mode**. See paragraph “Operation” on page 13 for more details
13	Standby key	When activated, the Vari-Lase laser console is set into **Standby Mode**. Parameters can be modified, but no laser output can be generated
14	Emergency stop key	See paragraph “Operation” on page 12

15		Laser ready indicator	Lit whenever the Vari-Lase laser console is emitting aiming light
16		Laser emission indicator	Flashing when laser emission occurs
17		Key switch	The laser unit is disabled when the key is in off-position or when the key is removed. Text “TURN KEY“ and a key symbol is displayed when the key is turned in off-position
18		Fiber connection	Laser pulses are delivered via a fiber assembly
19		Laser beam input port	Laser input port for verification purpose. See paragraph “Output Power Verification” on page 15
20		Display	Display used for displaying visual information to the user
21		Foot switch inlet	Air foot switch inlet and release button, situated on rear panel
22		Remote interlocking	Interlocking socket situated under the front panel. See paragraph “Remote Interlocking” on page 17
23	**A**	Service connector	Service connector A. Intended for service use only
24	**B**	Service connector	Service connector B. Intended for service use only
25	Power switch		
26	Fuse holder		
27	Power cable inlet		
28		Follow Instructions for Use	Instruction to follow the information in the instructions for Use See paragraph “Power Connection and Replacement of Fuses” on page 23.



Operation

Preparing for use

1. Plug the foot switch tube into the socket at the rear of the laser unit (21)
2. Insert the power cord at the rear of the laser unit (27)
3. Switch on the power switch at the rear of the laser unit (25)
4. Connect interlock or insert dummy plug in the connector (22), cf. “Remote Interlocking”
5. Enable the laser unit by inserting and turning the key in the switch (17). The aiming light will be activated and the indicator (15) will be lit
6. Visually inspect the QSC adapter lens for contamination or damage
7. Insert the SMA-to-QSC adapter in the Vari-Lase laser console.
8. Remove the protection cap from the Platinum Bright Tip laser fiber connector
9. Insert the Platinum Bright Tip laser fiber connector carefully in the SMA socket of the SMA-to-QSC adapter. Tighten the screw carefully
10. While the Vari-Lase laser console is powering up, laser emission is disabled, all keys and selectors are disabled. The Vari-Lase laser console is default set into **Standby Mode**

WARNING: Make sure the Platinum Bright Tip laser fiber is connected before firing the laser

11. Set the treatment parameters
12. Set the Vari-Lase laser console into **Ready Mode** by pressing the Ready key (12). After a required 3 seconds safety-delay the unit will become ready and the text in display will show READY
13. Start treatment by pressing the foot switch. Each time the foot switch is activated, laser radiation will be emitted and the Laser emission indicator (16) is lit

Setting of treatment parameters

Power, pulse width, and pulse repetition rate can be set to prepare for the required treatment.

The suggested application of total energy is 50-70 joules/cm. Power can be set in the range 0-15W in 1W increments with the recommended treatment level between 10-14W. (The output power level is shown in the display.) When fired in continuous mode, it is recommended that the fiber and/or sheath are pulled back along the length of the vessel at a rate of 5-7 sec/cm.

More specific parameters are not recommended, but are left to operator preference and best medical judgment dependent on the particular application.

The treatment parameter to be set is selected by pressing the associated selector (1, 3, or 4) located below the display. When a parameter is selected, it can be modified by turning the jog wheel.

When all parameters are properly set for treatment, press Enter (10) to store the parameters. One can also press the Ready key to store the parameters and bring the unit directly into **Ready Mode**.

Pressing the Back key (9) during setting of a parameter terminates the setting without changing the parameter.

Pulse width

Pulse width can be set in the range 10-3000msec. The pulse width is shown in the display.

Pulse repetition frequency

Frequency can be set in the range 0.3 - 100Hz. Further, output can be set to single pulse and CW. The frequency is shown in the display.

Standby Mode and Ready Mode

Ready

When the Ready key is pressed, the unit enters **Ready Mode**. In this mode, laser radiation will be emitted when the foot switch is pressed. When pulse length is shorter than 50msec, a steady audible tone will be generated twice a second. When pulse length is longer than 50msec, an audible tone will be generated when laser is emitted. Pressing the M, Back, or P key or any selector key will return the system to **Standby Mode**.

Standby

If the system remains idle in **Ready Mode** for 250 seconds, it will automatically return to **Standby Mode** for the sake of operator and patient safety.

When the Standby key is pressed, the unit enters **Standby Mode**. For safety reasons the laser should always be brought into **Standby Mode** whenever not treating. In **Standby Mode**, laser radiation cannot be emitted.

Start and stop of laser radiation

When the treatment laser is active, the yellow Laser emission indicator flashes and an audible tone signal will be heard.

Caution

When the Laser ready indicator is on, the Vari-Lase laser console emits aiming laser radiation.

READY

When the text in the display shows READY, the Vari-Lase laser console emits treatment laser radiation immediately upon activation of the foot switch.

Foot switch operated

When the foot switch is pressed, the Vari-Lase laser console starts radiating. Releasing the foot switch stops emission.

Emergency STOP key

When the emergency stop key (14) is pressed, the Vari-Lase laser console stops emitting laser radiation and all functions are blocked. The mains power switch (25) must be switched OFF for approximately 15 seconds and ON again for restart.

Shut down procedure

The Vari-Lase laser console is shut down by pressing the main power switch (25) on the rear of the unit.
The Vari-Lase laser console automatically detects that the main switch is pressed and the unit is brought into a safe state where a controlled shut down procedure is executed.
The shut down procedure can be initiated regardless of the state of operation.

Output Power Verification

The Vari-Lase laser console provides advanced built-in facilities for output power verification purpose.

1. Press the M key (6) to enter the Function Menu
2. Press the Right key (8) to enter the second Function Menu
3. Press the “Measure Power” selector (2)
4. Align the output tip of the fiber with the sensor opening (19) and keep it aligned during the entire measuring process
5. Activate the foot switch – and keep the foot switch pressed during the entire measuring process. Any measurement interrupted by the release of the foot switch will be ignored
6. The Vari-Lase laser console automatically tests the laser output by measuring the power level of a number of pulses – wait for this to complete
7. The measured optical output in watts is displayed

Repeated measurements may cause the built-in power meter to heat up. If so, a message will appear urging the user to wait 5 minutes before further measurements are undertaken.

Caution

All personnel in the operating room must wear protective eyewear during the measurement.

Definition and Retrieval of Treatment Parameter Sets

The Vari-Lase laser console features the possibility of defining sets of treatment parameters. These parameter sets can later be retrieved for fast unit setup.

This is an overview of the features of the treatment parameter function:

- 16 parameter sets can be stored
- Easy access, stored parameter sets can be retrieved with 2 button presses
- Each parameter set can have 2 lines of 8 characters to describe the use. The description is shown on the main screens
- After power off the parameter sets will still be available
- All parameters are saved including guide beam intensity, fiber diameter and fiber tip. Bare fibers are handled as part of treatment sets as well

Power up defaults

When powering up the MedArt® 700 laser unit the parameters in program 16 are always retrieved. The parameters in program 16 can be changed and stored by the user if different values are preferred. Note: the default program name “DEFAULT” isn’t stored if changed. The new default parameters will be active next time the MedArt® 700 laser unit is powered up.

Factory defaults are:

1W, CW (continuous wave)
Aiming light level 100%
Aiming light ON in **STANDBY** mode
Laser Energy Emission Every 70J
Laser Energy Emission Mark ON
Laser Energy Beep inc. 30%

Program function modes

The program function has 4 modes that are selected with repeated presses of the Program key (5).

First press:

Shows simple parameter screen with parameter set names only.

Press one of the 4 Selector keys (1-4) to recall the intended program or press the Left or Right keys (7, 8) to scroll between blocks of 4 parameters.

Second press:

Show detailed information about each program.

Again the Selector keys (1-4) recall a program and the Left or Right keys (7, 8) scroll.

Third press:

Press a Selector key (1-4) to save the current set of parameters.

Fourth press:

Press a Selector key (1-4) to change the name of the parameter set.

The set parameters will not be changed only the name.

Retrieving a parameter set

Go through the following steps to retrieve a predefined set of parameters:

1. Make sure the laser unit is in **Standby Mode**
2. Press the Program key (5)
3. The contents of the program memory slots are displayed on the screen. Press the Left, Right keys (7, 8) to access the remaining program locations
4. Press the Selector key (1-4) corresponding to the parameter set to be used
5. The previously saved parameter set is recalled and the laser unit is ready to be set into **Ready Mode**

Changing the name of a program

1. Make sure the laser unit is in **Standby Mode**
2. Press the Program key (5) 4 times
3. Press the Selector key (1-4) corresponding to the program who's name you wish to change. Use the Left, Right keys (7, 8) to access other program locations
4. Use the Left, Right keys (7, 8) and jog wheel (11) to change the name
5. Press Enter (10) to return to **Standby Mode**

Note: The name of program 16 is overwritten by system defaults at the next system power up.

Remote Interlocking

The Vari-Lase laser console provides an interlocking feature that can be employed for deactivation of laser emission when doors are opened to the treatment area.

If remote interlocking is not required

The unit is supplied with a special interlocking dummy plug that has to be inserted in the interlocking socket (22).

If remote interlocking is required

If the interlocking feature is required to ensure a safe entry to the treatment area, an appropriate switch may be mounted on the doorframe in a way that ensures contact closure when the door is closed.
Pin 1 and 6 in the interlocking socket must be connected to the switch and multiple doors can be wired in series if needed.

A special plug giving access to pin 1 and pin 6 in the interlocking socket (22) can be supplied by Vascular Solutions, Inc.

Connection and Release of Foot Switch

A connector (21) for the foot switch is provided on the rear panel. For connection simply plug-in the foot switch connector.
Release the foot switch by pressing the adjacent button.

System Setup and Status Display Controls

A number of system features, which may be setup by the user, exist. To do this please follow the below procedure:

1. Make sure the unit is in **Standby Mode**
2. Press the M key (6) to enter the 'Function menu 1'
3. Press Selector key (2) to enter the 'User Setup 1' menu

Four setup options are displayed. Press the Right key (8) or the Menu key (6) to display the last three options in 'User Setup 2'. These seven options are described below:

Sound Level

Turn the jog wheel (11) to change the volume of the internal speaker. Press the Enter key (10) when a satisfactory volume is found. For safety reasons the level cannot be set to values lower than 30%.

Display Contrast

Turn the jog wheel (11) to change the display contrast. Press Enter key (10) when a satisfactory display contrast is found.

Aiming Beam

Turn the jog wheel (11) to adjust the brightness of the aiming beam. Press the Enter key (10) when the desired brightness is found. The effect will be visible the next time **Ready mode** is entered.

Choose Language

Turn the jog wheel (11) to see the languages, which can be selected for display text. Press the Enter key (10) when the desired language is found.

Status Display 1/Status Display 2

The user can choose two selectable status readings to be displayed during operation. The two readings can be chosen from a group of four:

- None: No status is displayed
- Pulses: The number of pulses generated
- ActiveTime: The amount of time laser has been radiated
- Joules: The amount of joules generated

The one reading is chosen by using menu entry 'Status Display 1' and the other by using menu entry 'Status Display 2'. Use the jog wheel (11) to browse through the four options. Press the Enter key (10) when the desired status reading is found. The reading will be displayed whenever the unit is in **Standby** or **Ready Mode**.

Reset Counters

The user may want to reset the readings; e.g. before a patient treatment is initiated. To do this, please follow the below procedure:

1. Make sure the unit is in **Standby Mode**
2. Press the Menu key (6) to enter the 'Function menu 1'
3. Press Selector key (3) to reset the status display readings

Service/Adjustment Functions

The Vari-Lase laser console provides the user with various features for setting and reading of equipment parameters. These adjustable parameters are organized into six service groups that can be accessed when the unit is in **Service Mode**. Follow the below procedure to enter Service mode:

1. Make sure the unit is in **Standby Mode**
2. Press the Menu key (6) to enter 'Function menu 1'
3. Press the Right key (8) to enter 'Function menu 2'
4. Press Selector key (1) 'Service Setup'
5. The unit is now brought into **Service Mode**

The following six groups of service settings are accessible to the user:

USER SETTINGS

Standard user controls like display contrast, sound level, etc.

ACCESS CODES

Access codes can be entered for service or maintenance purpose. For safety reasons access is only granted to authorized personnel.

UNIT IDs

Reports various IDs associated with each individual Vari-Lase laser console

CODEPLUG SETTINGS

Standard user set-up values which are stored in the code plug. The code plug is memory location inside the laser unit inaccessible to the user.

TIME LOG

This group contains time logging and timing functions.

LASER SETUP/ADJ

Setup of aiming beam and laser mark functionality behavior.

Service mode controls

All Available **User Settings** will remain in English regardless of what language is selected for displayed text.

- Use the jog wheel (11) to browse the service settings
- Use the Left, Right keys (7, 8) to change from one group of service settings to another
- Use selector key (4) 'Change' to modify a parameter. Note: the change feature only exists for a subset of the parameters

There are two types of parameter input modes:

- *Limited range parameters*. Operate the jog wheel (11) to change the parameters. Press the Selector key (4) 'Save' to store the set value.
- *Large number selection*. Operate the jog wheel (11) to change the value of the current digit. Press the Right, Left keys (7, 8) to select another digit. Press the Selector key (4) 'Save' to store the set value

Available service settings are described in more detail by the following table.

USER SETTINGS	
100	**Sound Level** This setting changes the volume of the internal speaker. The volume changes instantly; but will not be saved until 'Save' is pressed
101	**Display Contrast** This setting changes the contrast of both displays. The contrast changes instantly; but will not be saved until 'Save' is pressed
102	**Language** This setting changes the language used for displayed text. The selected language is not saved until 'Save' is pressed
103	**Status Display 1** This setting features the selection of status reading 1 (as described on page 19) to be displayed
104	**Status Display 2** This setting features the selection of status reading 2 (as described on page 19) to be displayed
ACCESS CODES	
200	**Access Code** To be used by authorized service personnel only
UNIT IDs	
300	**Serial Number** The laser unit serial number is displayed
301	**Type Number** The laser unit type number is displayed
304	**SW Version** The laser unit software version is displayed
TIME LOG	
500	**Power On Time** Reports the total power-on time of the laser in minutes
501	**Laser Active Total Time** Reports the total Laser Active time at any power level in minutes
509	**Total Joules** Reports the total number of joules emitted from the laser
LASER SETUP/ADJUST	
709	**Aiming Beam Level** Brightness of the aiming beam. The brightness changes instantly, but will not be saved until "Save" is pressed.
711	**Aiming Beam in STANDBY mode** Defines whether or not the aiming beam is on in STANDBY mode. The aiming beam output changes instantly; but will not be saved until 'Save' is pressed.
712	**Laser Energy Mark Interval** Defines the amount of energy that must be emitted between each laser emission mark.

713	**Laser Energy Mark Beep inc,** Defines whether or not the laser emission mark is played with an increased sound level compared to the standard laser warning beep. The increased level can never exceed the system maximum 100% sound level.
714	**Laser Emission Mark** Defines whether or not the audible laser emission mark is enabled or not. If enabled, a laser emission mark is heard every time a certain amount of laser energy has been emitted corresponding to the value set in 712.

Cleaning and Maintenance

The Vari-Lase laser console requires no maintenance except for periodic calibration of the power meter.

Do not expose the laser unit or accessories to moisture or extremes of temperature or humidity. Do not attempt to sterilize any part of the equipment.

For a routine maintenance schedule, please refer to Appendix A.

Calibration of power meter

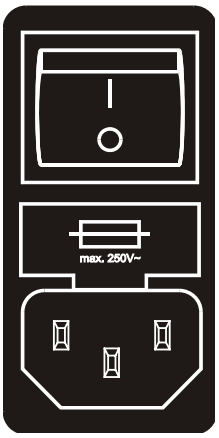
Every 24 months the power meter should be recalibrated. Contact Vascular Solutions, Inc. for details.

Cleaning

Clean the laser unit using a cloth moistened in a mixture of 30% alcohol and 70% water. Pure undiluted alcohol or detergents should not be used.

During cleaning, the laser unit must be switched off and disconnected from the power supply.

Power Connection and Replacement of Fuses



The laser unit is connected to power via the power cable inlet (27) on the back panel of the laser unit. The power switch (25) is used to switch the laser unit ON or OFF.

The unit is equipped with 2 pcs. glass fuses (T1.6AL), which protect the laser unit in case of electrical fault. If the unit cannot be switched ON, try to replace the fuses before the unit is handed in for repair.

To replace the fuses:

1. Remove the power cord
2. Pull out the fuse box (26)
3. Replace the fuses and re-insert the fuse box
4. Close the fuse box

Use only Ø5x20mm T1.6AL fuses

NOTE: The Vari-Lase laser console must always be grounded.

Trouble Shooting

Symptom	Possible Cause	Recommendation
No light in display when switched on	• Defective power fuses • Low power supply	• Change fuses • Wait minimum 5sec for power up
Low output power	• Defective fiber • Defective QSC • Low pulse width combined with low frequency	• Change fiber • Change QSC • Choose higher pulse width
A temperature fault message is displayed and the Vari-Lase laser console stops radiating	• Overheated diode due to combination of high room temperature, high power setting and high duty cycle • Internal laser cooling system ineffective	• Wait a few seconds for the system to cool down. If the problem remains, try to reduce room temperature. Reduce output power. Reduce duty cycle (shorter dwell time, longer breaks). • Return for repair

Aiming beam has faded or is looking diffused	• As the aiming beam passes through the same optical system as the working beam, it provides a good method of checking the unit. If the aiming beam spot is not present at the distal end of the fiber, its intensity is reduced or it looks diffused, the fiber might be damaged.	• Check the unit by undertaking an output power verification as described in the paragraph “Output Power Verification” on page 15.

Warnings and Stop Codes

The table below provides a complete overview over the various warnings and stop messages that can be displayed by the Vari-Lase laser console. If one of the messages appears repeatedly, note the message and call Vascular Solutions, Inc.

Error code	Error message	Cause	Recovery
0	**EMERGENCY STOP**	Emergency button has been pressed	Laser shuts down. Cycle power switch to recover
1	**I/O SYSTEM STOP**	This is an internal laser system situation	Laser shuts down. Cycle key switch to recover
3	**OVER CURRENT STOP**	This is an internal laser system situation	All laser circuits are shut down. Cycle key switch to recover/retry. Note: Do not repeatedly provoke an over-current stop; the laser diodes could be damaged. Reduce power and retry
4	**POWER HIGH STOP**	This is an internal laser system situation	Laser shuts down. Cycle key switch to recover
5	**POWER LOW STOP**	This is an internal laser system situation	Laser shuts down. Cycle key switch to recover
6	**VDIODE STOP**	This is an internal laser system situation	Laser shuts down. Cycle key switch to recover
7	**POWER DOWN**	Power supply output voltage low	Saves data internally and shuts down system. Check power
8	**DIODE TEMPERATURE STOP**	Laser diode temperature is too high	The laser is shut down. Normal operation will resume when temperature is reduced
12	**CONNECT FIBER**	All laser controls are disabled until a fiber is inserted	Resumes normal operation when the fiber is inserted

13	**CONNECT INTERLOCK**	All laser controls are disabled until an interlock connector/switch is installed. Pin 2 (GND) and 5 (Interlock input) must be shorted on the interlock connector	Resumes normal operation when connected
16	**CONNECT FB SENSOR**	This is an internal laser system situation	Laser shuts down. Cycle key switch to recover
17	**PARAMETER STOP**	Parameter(s) in the internal code plug or laser is out of range. Pressing the Standby key (13) will initialize the parameters to default values	Laser output is disabled. Resumes normal operation when standby has been pressed
18	**SAFETY PARAMETER STOP**	This is an internal laser system situation	Laser shuts down, Cycle key switch to recover
22	**LASER TEMPERATURE TOO LOW**	Internal system temperature too low	Switch off the system and let reach room temperature before powering up

NOHD (Nominal Optical Hazard Distance) and MPE

The Nominal Optical Hazard for the system is calculated.
The basis for this calculation is the wavelength of the system, the max power, and the parameters of the delivery system.
The MPE (Maximum permissible exposure) is also calculated.

	Bare Fiber 600µm-0.37	Bare Fiber 600µm-0.22	Bare Fiber 400µm-0.22
N.A. - Numerical aperture	0.37	0.22	0.22
Divergence ϕ	0.76rad	0.45rad	0.45rad
Optics	1.0mm	1.0mm	1.0mm
NOHD	**1.4m**	**2.4m**	**2.4m**
Spot area in 10cm	43cm^2	15cm^2	15cm^2
E_{10cm} Irradiance in a distance of 10cm, measured in 7mm aperture	3,5kW/m^2	10kW/m^2	10kW/m^2
MPE - E_{mpe}	**16.8W/m^2**	**16.8W/m^2**	**16.8W/m^2**
Required damping Log(E_{10cm}/ E_{mpe})	2.3	2.8	2.8
Min. protective eye wear	L3	L3	L3

Protective Eye Wear

Protective eyewear must be of a quality corresponding to the standards IEC 60825 and EN 207.

According to these specifications, the protective eyewear must be marked with the following:

Type of laser:	D	continuous wave laser
Wavelength:	800-830 nm	or larger wavelength interval
Protective class:	L3	or higher

Service

In the event of malfunction or fault, please contact Vascular Solutions, Inc. Customer Service at 888-240-6001 or 763-656-4300.

Storing and Transportation

The laser unit must be stored under temperature conditions in the range of -10 – +50°C (14 – 122°F) air humidity below 80% and air pressure in the range of 70kPa – 150kPa

If transporting the laser unit, the Vari-Lase laser console should always be transported in the original packaging material.

Technical Specifications for the Vari-Lase laser console

Type no.:	Vari-Lase Endovenous Laser Console 7550
Laser type:	Continuous Wave Diode Laser. Laser Class 4 (IEC 60825)
Output power:	
Range:	1W to 15W in steps of 1W
Maximum:	15W, depending on transmission in connected fiber
Precision:	Better than 10% at maximum output power
Mode of operation:	Continuous wave or pulsed beam
Wavelength:	810 nm ±10nm
Target indicator:	Red indicator light through fiber 635nm Can be enabled when the laser is in **Standby** mode
Fiber connection:	SMA-905 / Quick Safe Connect (QSC)
Fiber diameter:	400µm, 600µm, & 1,000 µm
Numerical aperture of fiber:	0.22 or higher
Start/stop functions:	Foot switch
Emergency stop:	Large button on front panel
Warning signal for aiming light radiation	Yellow indicator on the front panel
Warning signals for laser radiation:	Flashing yellow indicator and intermittent sound
Laser Ready warning:	Text READY in display, yellow indicator on front panel and target indicators
Laser Ready timeout:	250 seconds
Emission:	
Frequency range:	0.3 – 100Hz
Pulse width:	10 - 3000msec
Nominal Ocular	0.22NA fiber → NOHD = 2.4m
Hazard Distance:	0.37NA fiber → NOHD = 1.4m
Beam divergence:	QSC output: 0.45 rad
Acoustical mark:	Unique beep sequence after emission of 10 – 500J Volume level increase 0 – 70% Acoustical mark can be enabled or disabled
Output power meter:	
Range:	1W to 150W
Accuracy:	Better than ±20%
Protection against ingress of water:	Class IPX0
Power supply:	Power connection (100-240VAC, 50/60 Hz)

	North America: use center-tapped circuit when connecting the equipment to 240V, single-phase power
Power consumption:	30 - 150VA
Indication of mains power ON:	Display is lit
Fuses:	2 pcs. T1.6AL, Ø5x20mm
Patient leakage current:	Typically 0 µA (< 100 µA)
Earth leakage current:	Typically 150µA (< 300µA) < 300µA at 110V and at center-tapped 240V
Operating environment:	Room temp. 15-27°C/ 59-81°F Humidity 10-80%, Air pressure 70kPa – 150kPa
Safety class:	I type BF
Application in presence of flammable anesthetic mixtures:	Not suited
Size:	30 x 27 x 17 cm
Weight:	Approx. 4.5kg (10lb)
EMC regulations and testing:	EMC specifications are tested under the following conditions: • Air foot activator was used • Interlock function was connected to a 3m twisted pair of shielded cables • Connected optical fiber was found to be of no influence to the EMC test results

The system is developed and tested in accordance with the following regulations, covering software, electrical and laser safety:

EN 60601-1 + A1	Electrical safety
EN 60601-1-1	Medical electrical equipment
EN 60601-1-4, 2nd edition	Medical systems with software
IEC 60601-2-22	Particular requirements for the safety of diagnostic and therapeutic laser equipment
IEC 60825-1, 2nd edition	Safety of laser products
IEC 62304, 3rd edition	Medical device software

The following regulations and standards have been used to obtain the necessary EMC approvals:

IEC 60601-1-2	EMC standards

Guidance and manufacturer's declaration – EMC topics

Guidance and manufacturer's declaration – electromagnetic emissions		
The Vari-Lase laser console is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Vari-Lase laser console uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Vari-Lase laser console is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Vari-Lase laser console is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30% RH.
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines ± 1kV for input/output lines	Power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV differential mode ± 2kV common mode	± 1kV differential mode ± 2kV common mode	Power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	Power quality should be that of a typical commercial or hospital environment. If the user of the Vari-Lase laser console requires continued operation during power interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC power voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Vari-Lase laser console is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms 150kHz to 80MHz 3V/m 80MHz to 2.5GHz	3Vrms 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Vari-Lase laser console, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80M to 800MHz $d = 2.3\sqrt{P}$ 800M to 2.5GHz where *P* is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1: At 80MHz and 800MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Vari-Lase laser console is used exceeds the applicable RF compliance level above, the Vari-Lase laser console should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Vari-Lase laser console. [b] Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the Vari-Lase laser console

The Vari-Lase laser console is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Vari-Lase laser console can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Vari-Lase laser console as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter / W	**Separation distance according to frequency of transmitter / m**		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	**80MHz to 800MHz** $d = 1.2\sqrt{P}$	**800MHz to 2.5GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix A

Table A-1
Routine Maintenance Schedule

Service	Frequency	Performed by
Check the exterior of the unit making certain that there are no loose electrical connections or damage	Daily	Clinic or hospital staff
Test of fiber	Daily	Clinic or hospital staff
Verify output power (see page 15)	Daily	Clinic or hospital staff
Perform power meter and laser output Calibration. Check that power-meter has an accuracy of 20% or better. Check that laser output has an accuracy of 10% or better. Use an external calibrated power-meter for both checks.	Every 24 months	Vari-Lase laser console manufacturer authorized personnel only

Table A-2
Power Meter Calibration Procedure

Note: This chapter highlights the instructions for the Verification of Calibration of the Vari-Lase laser console. These instructions are provided to comply with Federal Regulations.

These procedures should be performed only by the Vari-Lase laser console manufacturer or a duly authorized representative, trained by the Vari-Lase laser console manufacturer. Calibration verification performed by any other individual will void any manufacturer's warranty, stated or implied.

1. Enter **Service Mode**
2. Set the “Power Meter Gain” setting 800 to: 100%
3. Check that the power meter temperature is close to ambient temperature (±3°C). The power meter temperature can be read from service setting 802. Set the measurement power to 0W and start the power measurement by pressing Ready. The power meter temperature is displayed at the end of the measurement cycle.
4. Set the laser power to 15W using service setting 705 and measure the output power using an external calibrated power meter
5. Point the fiber at the internal power meter and measure the power using service setting 802
6. Set the “Power Meter Gain” setting 800 to:

$$\text{Power Meter Gain} = \frac{\text{External power meter reading}}{\text{Internal power meter reading}} \times 100$$

Note: The “Power Meter Loss” is as default set to 0.1 from factory and should not be changed. This value is based on the power meter material properties.